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(54) Stent-crimping tool and method of use

Werkzeug zum Komprimieren eines Stents und Verfahren zum Gebrauch

Outil pour comprimer un stent et procédé d'utilisation

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Description

[0001] This invention relates to a stent-crimping device and method of using the device that enables an end user to firmly crimp a stent onto the distal end of a catheter assembly.

[0002] In a typical percutaneous transluminal coronary angioplasty (PTCA) procedure for compressing lesion plaque against the artery wall to dilate the arterial lumen, a guiding catheter is introduced percutaneously into the cardiovascular system of a patient through the brachial or femoral arteries and is advanced through the vasculature until the distal end is in the ostium. A guide wire and a dilatation catheter having a balloon on the distal end are introduced through the guiding catheter with the guide wire sliding within the dilatation catheter. The guide wire first is advanced out of the guiding catheter into the coronary vasculature of the patient, and the dilatation catheter is advanced over the previously advanced guide wire until the dilatation balloon is properly positioned across the lesion. Once in position across the lesion, a flexible, expandable, pre-formed balloon is inflated to a pre-determined size at relatively high pressures to radially compress the atherosclerotic plaque of the lesion against the inside of the artery wall and to thereby dilate the lumen of the artery. The balloon then is deflated to a small profile, so that the dilatation catheter can be withdrawn from the vasculature of the patient and blood flow resumed through the dilated artery. While this procedure is typical, it is not the only method used to accomplish an angioplasty procedure. Further, other methods are well known to open a stenosed artery, such as atherectomy procedures, plaque-dissolving drugs, and the like.

[0003] In angioplasty procedures of the kind referenced above, restenosis of the artery may occur, and a further angioplasty procedure, a surgical bypass operation, or some method of repairing or strengthening the area may be required to treat the restenosis. To reduce the chance of restenosis and to strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, such prosthesis typically being referred to as a stent. A stent is a device used to hold tissue in place, or to provide support for a graft or for tissue joined while healing is taking place. A variety of devices are known in the art for use as stents, including coiled wires and wire mesh sleeves, in a variety of patterns, that can be crimped onto a balloon catheter, and then expanded after being positioned intraluminally on the balloon catheter, and which have the capacity to retain the expanded form. Typically, the stent is mounted and crimped onto the balloon portion of the catheter and then advanced to a location inside the artery at the lesion. The stent then is expanded to a larger diameter by the balloon portion of the catheter, in order to implant the stent in the artery at the lesion. Examples of stents and delivery catheters of the type described herein are disclosed in more detail in U.S. Patent No. 5,102,417

(Palmaz); U.S. Patent No. 5,514,154 (Lau et al.); and U.S. Patent No. 5,569,295 (Lam).

[0004] If the stent is not tightly crimped onto the catheter balloon portion, however, when the catheter is advanced in the vasculature, the stent may slide off the catheter balloon portion in the coronary artery prior to expansion, and thereby may block the flow of blood, necessitating procedures to remove the stent.

[0005] In procedures where the stent is placed over the balloon portion of the catheter for delivery, the stent first must be crimped onto the balloon portion to prevent the stent from sliding off the catheter when the catheter is advanced in the vasculature of the patient. In the past, the crimping procedure often was done by hand, which tended to result in uneven force being applied, such that the stent was not crimped onto the balloon uniformly. In addition, hand crimping makes it difficult to determine when a uniform and reliable crimp has been applied or whether the stent has damaged the balloon as a result of the crimping process. Though some tools, such as ordinary pliers, have been used to crimp a stent onto a balloon, these tools have not been entirely adequate in achieving a uniform crimp.

[0006] Some specialist crimping tools have been designed. For example in EP-A-0,630,623 there is described a stent-loading mechanism for automatically loading a stent onto a balloon delivery catheter. The device comprises a pair of plates having substantially flat and parallel surfaces that move in a rectilinear fashion with respect to each other. A stent-carrying catheter can be disposed between these surfaces to affix the stent onto the outside of the catheter by providing relative motion between the plates. The plates may have multiple degrees of freedom and force-indicating transducers to measure and indicate the force applied to the catheter during affixation of the stent.

[0007] Another embodiment of the stent-loading mechanism comprises a tubular member housing an elongated elastic bladder that surrounds the stent to be loaded. The distal end of the balloon catheter assembly and the stent are placed inside the tubular member and pressurized fluid is applied to the bladder to compress and affix the stent onto the outside of the catheter assembly.

[0008] Crimping tools are also known in other fields. US-A-5,195,539 describes a device for compressing slow recovery earplugs. The device comprises a flexible strip having an elongate compression portion having first and second ends and a base portion at the first end of the compression portion. The base portion has a width greater than that of the compression portion. An opening is provided proximate the compression portion having a width transverse of the compression portion larger than the width of the compression portion. The compression portion is at least 15mm wide and of sufficient length that the second end can pass through the opening to form a tubular compression means having a diameter at least that of a slow recovery earplug.

[0009] Nevertheless, there remains a need for improved tools and methods to secure stents onto the balloon portions of catheters.

[0010] This invention is directed to a vascular prosthesis crimping device or tool which enables a stent to be crimped onto the balloon portion of a catheter in a substantially uniform and tight manner, to better secure the stent onto the catheter for delivery of the stent through the vasculature of a patient, while at the same time permitting uniform expansion of the stent in an artery or a vein, duct, or other vessel or lumen. The present invention solves several deficiencies that have been experienced with prior art methods of crimping stents onto the balloons of balloon catheters.

[0011] According to a first aspect of the present invention there is provided a stent-crimping tool having the features set out in claim 1.

[0012] In an exemplary embodiment of the present invention, the stent-crimping tool includes a radially compressible and resiliently and radially expandable cylindrical loop portion having opposed side edges extending from the loop portion. These side edges are secured to pivoting arm portions of the device. A user can inwardly and radially compress the inner diameter of the loop portion by moving the pivoting arm portions downwardly to substantially uniformly and tightly crimp the stent onto the balloon catheter assembly which is inserted within the loop portion. The loop portion is returned to its expanded state by bringing the pivoting arm portions back to the un-pivoted position, thereby allowing the crimped stent-and-balloon-catheter assembly to be withdrawn by the user.

[0013] The stent-crimping tool enables the stent to be crimped onto the distal end of a balloon catheter substantially uniformly and tightly, reducing the risk that the stent may shift or slide off the balloon portion of the catheter during delivery. The tool is easy to use and is particularly well suited for use in compressing stents onto balloon catheters of different manufacturers, due to its simplicity, low manufacturing and assembly cost, an adaptability to compressing stents of different length and diameter. For the same reasons, the tool is ideally suited as a one-time use disposable crimping tool, thereby eliminating the need for sterilization of the device between uses.

[0014] These and other advantages of the invention will become apparent from the following detailed description, when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIGURE 1 is a perspective view of an exemplary embodiment of the present invention, in its open position, in which the loop portion of the device is fully expanded for receipt of a stent to be compressed onto a balloon catheter.

[0016] FIG. 2 is a top plan view of the main body por-

tion of the embodiment illustrated in FIG. 1.

[0017] FIG. 3 is a cross-sectional view through the view lines 3-3 of FIG 2.

5 [0018] FIG. 4 is a perspective side view of the loop portion of a stent-crimping tool according to the invention in the threaded orientation.

[0019] FIG. 5 is a plan view of the sheet of material forming the loop portion of the stent-crimping tool of FIG. 4 prior to being threaded.

10 [0020] FIG. 6 is a bottom view of the clips of a stent-crimping tool according to the invention which are used to secure the loop portion to the main body portion.

[0021] FIG. 7 is a side view of the securing clips as illustrated in FIG. 6.

15 [0022] FIG. 8 is a side view of a stent-crimping tool according to the invention packaged to maintain its loop portion, in its open position, wherein the loop portion cannot be radially compressed.

[0023] FIG. 9 is an exploded side view of the parts of 20 a stent-crimping tool according to the invention, prior to final assembly, and the packaging thereof.

[0024] FIG. 10 is a side view of a stent-crimping tool according to the invention, with packaging removed, illustrating the tool in the open position prior to radial compression of the loop portion.

25 [0025] FIG. 11 is a side view of the stent-crimping tool of FIG. 10, with the arm portions of the main body portion pivoted downwardly away from the intermediate portion so as to cause the loop portion to constrict in diameter 30 and to thereby crimp a stent around the balloon portion of the catheter which has been positioned within the loop portion.

[0026] The invention comprises a tool 10 and method of using a tool that is useful in uniformly and tightly 35 crimping an intravascular stent A onto the collapsed balloon portion B of a balloon catheter assembly D, which balloon is adjacent the distal end C of the catheter assembly. In the exemplary embodiment as illustrated in FIGS. 1 and 10, the tool 10 is adapted to be held in the 40 hand of the user. The user will insert the stent A, which previously has been placed over the collapsed balloon B, into the loop portion 12 of the tool 10 to enable the stent A and the catheter D to be supported in the tool, and to enable the user to apply compressive force to the 45 tool to substantially uniformly and tightly crimp the stent A onto the collapsed balloon B of the catheter D.

[0027] The loop portion 12 of the tool 10 is affixed to a base portion 14. The circumference of the loop portion 12 is variable. The base portion 14 has an intermediate 50 portion 16 which is pivotally connected to two pivoting arm portions 18 and 20. The base portion 14 has a top surface 22 on which the loop portion 12 rests. The base portion 14 ideally comprises a single flat piece of material, such as plastic, with a pair of parallel, longitudinal, 55 V-shaped slits 26 and 28 extending from the top surface 22 almost all the way to the bottom surface 24, the slits 26 and 28 each terminating in a lower parallel edge 30, 31, such that each slit forms a hinge 30A, 31A to permit

the pivoting arm portions 18 and 20 to swing downwardly away from the intermediate portion 16. When the base portion 14 is formed from a single piece of plastic (or metal), then the hinges 30A and 30B can be said to be living hinges formed in base portion 14. Alternatively, the base portion 14 and the pivoting arm portions 18,20 can be formed separately and then hinges of conventional design can be added to connect the pivoting arm portions to the base. Referring to FIGS. 2 and 3, pivoting arm portions 18 and 20 each have a first engagement means, for example slots 32, formed in the top surface 22 of the base portion 14. A recess 34 is formed on one or more of the side edges 36 of each pivoting arm 18, 20, as is best shown in FIG. 2. A clip portion 38 is used to secure the loop portion 12 to the base portion 10 on each pivoting arm.

[0028] Referring to FIGS. 4 and 5, a preferred embodiment of loop portion 12 is shown in greater detail. The loop portion 12 comprises a sheet 44 of thin and flexible yet strong material, such as the polyester film sold under the trademark "MYLAR" by E.I. duPont deNemours and Company, and has a plurality of elongate straps 40 extending from a first end 42 of the sheet 44 and extending opposite a second end 46 of the sheet 44. Other known flexible materials can be used. Apertures 48 formed in the sheet 44 are adapted to receive the straps 40 when threaded therethrough, as shown in FIGS. 1 and 4, thereby forming a generally cylindrical opening 50 for receiving a stent A after it has been placed on the distal end C of the balloon catheter assembly B. Each strap 40 has a terminal end region 52. By pulling the terminal end regions 52 of the straps 40 and the second end 46 of the sheet 44 away from each other, the generally cylindrical opening 50 will constrict in size, from its larger size shown in FIGS. 1, 4, 8 and 9, to the constricted size shown in FIG. 10.

[0029] As seen in FIG. 5, the distance X between the aperture 48 and the first end 42 of the sheet 44 will determine the smallest possible diameter of the loop portion 12. Those skilled in the art will appreciate that the distance X can be varied, depending upon the diameter of the stent and of the balloon, and ultimately upon the diameter of the stent on the balloon after crimping. The thickness of the polyester film forming the loop portion 12 is an important consideration as to the capacity of the loop to rebound open after the stent is crimped. Thus, the polymer film preferably has a thickness in the range of 0.05 to 0.20mm (0.002 to 0.008 inches). With this range of thickness for the polymer film, it is flexible and durable, and will readily rebound open to return the loop portion 12 approximately to its starting diameter after the crimping procedure has been accomplished and the stent-and-balloon-catheter assembly have been removed from the tool.

[0030] In a preferred embodiment of the invention, the straps 40 can be about 5 mm wide (0.2 inches), with about 2.5 mm (0.1 inches) of open space between each strap and an adjacent strap. The entire length of the

sheet 44, the length of the straps 40 and the spacing of the apertures 48 from the first end 42, can be chosen depending on the size of the loop portion 12 desired. In lieu of a sheet of polyester film or other sheet material, 5 a plurality of wires or cords can be utilized to form the loop portion 12.

[0031] The end regions 52 of the elongate straps and the second end of the sheet 44 forming the loop portion 12 are secured to the tool 10 for radially compressible 10 and expandable movement as follows. Referring to FIGS. 2, 3, 6 and 7, the engagement means or slots 32 formed on the top surface 22 of the pivoting arm portions 18 and 20 (FIGS. 2 and 3), are adapted to receive a complementary engagement portion, for example, the 15 bar portion 54 which extends from a bottom surface 56 of the clip portion 38. The clip ends 58 are formed on the ends of the clip portions 38 (FIGS. 6 and 7). After placing the loop portion 12 on the top surface 22 of the intermediate portion 16 and extending the terminal end 20 regions 52 of the elongate straps 40 and second end 46 of the sheet 44 over the slots 32 in the pivoting arms 18, 20, the clip portions 38 are snapped onto the pivoting arms 18, 20 the complementary bar portions 54 fitting into the appropriate slots 32 and clip ends 58 fitting into recesses 34. This secures the terminal end regions 52 25 of the elongate straps 40 and the second end 46 of the sheet 44 comprising the loop portion 12, yet allows the portion of loop portion defining the generally cylindrical opening 50 to change configuration unencumbered by riding on the intermediate portion 16. In addition to this 30 mechanical affixation, adhesives and other means can be utilized to secure the elongate straps 40 and the end regions 52 thereof to the base portion 14. An advantage of stent-crimping tool the described is that the components comprising it, e.g., the base portion 14, the loop portion 12 and the clip portions 38 are all relatively low 35 in cost, and the base portion 14 and the clip portions 38 will accommodate a loop portion 12 of the desired diameter and length, to accept a balloon catheter D and a stent A of desired diameter and length.

[0032] Referring to FIG. 8, the top surface 22 of the base portion 14, the clip portions 38, and the loop portion 12 are covered with a protective layer 60 which cushions the top surface 22 and the loop portion 12, and prevents the loop portion 12 from being inadvertently crushed. The protective layer 60 can comprise bubble pack material, a vacuum-formed plastic cover, or other known materials. To prevent the pivoting arms 18, 20 and the intermediate portion 16 of the base portion 14 from being pivoted, a rigid support sheet 62 preferably is positioned on the bottom surface 24 of the base portion 14. Other means can be provided to protect the stent-crimping tool 10, such as a case or box to surround the device in a sterile environment. FIG. 9 is an exploded side view 45 of the stent-crimping tool 10 and its packaging. FIG. 10 shows the stent-crimping tool 10 after it has been removed from the packaging (including the protective layer 60 and the rigid support sheet 62) and ready for use.

[0033] Referring to FIGS 1 and 11, in a preferred method of operation, a user will load a stent A onto a deflated (unused) balloon portion B of a balloon catheter assembly D. The balloon catheter assembly then is inserted into stent A, such that stent A overlies the balloon portion B. To enable the stent A to be crimped onto the catheter balloon portion B, the stent A and the balloon portion B are inserted within loop the portion 12 and supported in the middle of the loop portion 12 which is carried on the intermediate portion 16 of the base portion 14. At this point, the stent A is not fixed onto catheter assembly D, because a stent A has not been compressed.

[0034] To crimp stent A onto the catheter balloon portion B, the user of the stent-crimping tool 10 simultaneously swings pivoting arm portions 18, 20 downwardly together relative to the intermediate portion 16. Pivoting arm portions 18, 20 downwardly causes the terminal ends 52 of the elongate straps 40 and the second end 46 of the sheet 44 to be pulled in opposite directions in a noose-like manner. The elongate straps 40 and the sheet portion 44 on the sides of the loop portion 12 will extend between opposite edges 64 and 66 of intermediate portion 16 and pivoting arm portions (18, 20), respectively. As swinging arm portions 18, 20 are swung down from an intermediate portion 16, the generally cylindrical opening 50 in the loop portion 12 will constrict to a smaller inner diameter, compressing a stent A radially inwardly and tightly onto the balloon portion B at a substantially uniform rate.

[0035] If further crimping of the stent A onto catheter the balloon portion B is desired, the user may rotate the crimped stent A and the catheter balloon portion B and/or the stent and the catheter balloon portion forward or backward in the loop portion 12, and repeat the crimping procedure until the stent A is as tightly crimped onto catheter balloon portion B as desired.

[0036] After the stent A has been crimped onto the catheter balloon portion B, the user will swing pivoting arm portions 18, 20 back up, thereby enlarging the generally cylindrical opening 50 and permitting the balloon catheter assembly with the crimped stent thereon to be removed from the generally cylindrical opening 50. The balloon catheter assembly D, with the stent A crimped thereon, then may be inserted into the body of the patient for deployment of the stent A (deployment is not illustrated in the drawing figures).

[0037] As will be appreciated by those skilled in the art, the stent-crimping tool of the present invention is designed both for single use applications in a catheterization lab, or for multiple use applications in a sterile environment in a high-volume manufacturing facility. In the manufacturing environment, where sterile conditions exist, the stent-crimping tool can be used to repeatedly crimp stents onto balloons until the polyester film wears out and has to be replaced. Thus, repeated uses are contemplated for controlled sterile environments, however, single use applications are required

when used by catheterization lab physicians or other medical personnel.

[0038] While in the preferred embodiments the stent referenced herein is intended to be an intraluminal vascular prosthesis for use within a blood vessel, and the balloon catheter assembly is of the type commonly used in therapeutic coronary angioplasty procedures, it will be appreciated by those skilled in the art that modifications may be made to the present invention to allow the present invention to be used to load any type of prosthesis. The present invention is not just limited to stents that are designed to be deployed in the vasculature of a patient, but can be used to crimp any type of graft, prosthesis, liner or similar structure onto a delivery device or other apparatus. Further, the stent may be intended for delivery not only into coronary arteries, but also into any other body lumen. Other modifications can be made to the present invention by those skilled in the art without departing from the scope thereof.

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Claims

1. A stent-crimping tool (10) to temporarily affix a stent (A) onto a catheter assembly (D), comprising:
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 - a base portion (14) having an arm intermediate portion (16) and pivoting portions (18,20) pivotally attached to the intermediate portion, and a loop portion (12) attached to the pivoting arm portions (18,20), for use in supporting a portion of the catheter assembly (D) on which the stent is to be loaded, the loop portion (12) having a compressible and generally cylindrical opening (50) which is substantially uniformly compressible radially inwardly, upon the application of force to the said pivoting arm portions, to substantially uniformly and tightly crimp the stent onto the catheter assembly.
 - 2. The stent-crimping tool (10) of claim 1, wherein the loop portion (12) comprises a sheet of flexible material (44) having first and second end portions (42,46), the first end portion comprising a plurality of elongate straps (40) extending from the first end portion of the sheet to terminal end regions (52), the sheet (44) having apertures (48) formed therethrough, wherein the elongate straps are threaded through the apertures formed in the sheet to establish the generally cylindrical opening (50), the opening being adapted to constrict when the elongate straps (40) and the second end (46) of the sheet are pulled in opposite directions.
 - 3. The stent-crimping tool of claim 2, further comprising a pair of clips (38) for affixing the terminal end regions (52) of the elongate straps (40) and a portion of the second end (46) of the sheet (44) of the

- loop portion (12) to the pivoting arm portions, with the generally cylindrical opening (50) riding on the intermediate portion (16).
4. The stent-crimping tool (10) of claim 3, wherein each pivoting arm portion (18,20) has an engagement means (32) formed thereon and wherein the clips (38) have complementary engagement portions (54) adapted for engagement with the pivoting arm engagement means to retain the terminal end portions (52) and the second end (46) of the sheet (44) of the loop portion (12) that are positioned theron. 5
5. The stent-crimping tool (10) of claim 4, wherein the sheet of flexible material (44) further has a top surface (22) and each pivoting arm portion (18, 20) further has a plurality of side edges (36) each side edge having a recess (34) disposed therein, and the engagement means (32) comprises a slot formed in the top surface for each pivoting arm portion, and the complimentary engagement portions (54) of the clips (38) each have a bar positioned on bottom surface (56) thereof adapted to fit into a corresponding slot (32), and a plurality of clip ends (58) adapted to fit into the recesses (34) in the side edges (36) of the pivoting arm portions (18,20). 10
6. The stent-crimping tool (10) of claim 1, further comprising a protective layer (60) which covers the loop portion (12) and which prevents the pivoting arm portions (18, 20) from being prematurely pivoted downwardly from the intermediate portion. 15
7. The stent-crimping tool (10) of claim 1, wherein the base portion (14) is formed from a single block of generally rigid material, wherein the pivoting arm portions (18, 20) and the intermediate portions (16) are formed by longitudinal slots (26, 28) formed in the rigid material extending from a top surface (22) to near a bottom surface (24) of the single block of material, leaving unsloated areas of material defining a pair of hinges (30A, 30B), so that in use, the pivoting arm portions can be pivoted on the pair of hinges. 20
8. A method of substantially uniformly and tightly crimping an intravascular stent (A) onto a catheter assembly (D), comprising the steps of: 25
- providing a device (10) comprising a base portion (14) having an intermediate portion (16) and pivoting arm portions (18, 20) attached to the intermediate portion, and a loop portion (12) for use in supporting a portion of the catheter assembly (D) on which the stent (A) may be positioned, the loop portion having a compressible and generally cylindrical opening (50) which 30
- is substantially uniformly compressible radially inwardly upon the application of force thereto to substantially uniformly and tightly crimp the stent onto the catheter portion, the loop portion having end portions (42, 46) attached to the pivoting arm portions; 35
- placing a portion of the catheter assembly, on which the stent is positioned, within the loop portion;
- pivotal moving the pivoting arm portions relative to the intermediate portion to move the end portions of the loop portion in opposite directions thereby reducing the diameter of the generally cylindrical opening to apply compressive force to compress the stent radially inwardly, to substantially uniformly and tightly crimp the stent onto the catheter portion; and
- releasing the compressive force to enable radially outward expansion of the generally cylindrical opening to enable the stent and catheter assembly to be withdrawn. 40
9. The method of claim 8, wherein the loop portion (12) comprises a sheet of flexible material (44), having first and second end (42, 46), the first end portion having a plurality of elongate straps (40) extending from the first end portion of the sheet to terminal end regions (52), the sheet having apertures (48) formed therethrough, wherein the elongate straps are threaded through the apertures formed in the sheet to establish the generally cylindrical loop opening, which loop opening is configured to constrict when the elongate straps and the second end (44) of the sheet are pulled in opposite directions. 45
10. The method of claim 8, wherein the device is covered with a removable protective layer (60) to protect the loop portion (12) and to prevent the pivoting arm portions (18, 20) from prematurely pivoting from the intermediate portion. 50

Patentansprüche

- 45 1. Stent-Krimpwerkzeug (10) zum vorübergehenden Befestigen eines Stents (A) auf einer Katheteranordnung (D), umfassend:
- einen Basisabschnitt (14) mit einem Mittelabschnitt (16) und Schwenkarmabschnitten (18, 20), die an dem Mittelabschnitt schwenkbar angebracht sind; und
- einen Schleifenabschnitt (12), der an den Schwenkarmabschnitten (18, 20) angebracht ist, um bei Gebrauch einen Abschnitt der Katheteranordnung (D) zu halten, auf dem der Stent angebracht werden soll, wobei der Schleifenabschnitt (12) eine komprimierbare 55

- und allgemein zylindrische Öffnung (50) aufweist, die beim Ausüben von Kraft auf die Schwenkarmabschnitte im Wesentlichen gleichmäßig radial einwärts komprimierbar ist, um den Stent im Wesentlichen gleichmäßig und dicht auf die Katheteranordnung zu krimpen.
2. Stent-Krimpwerkzeug (10) nach Anspruch 1, wobei der Schleifenabschnitt (12) ein Blatt aus flexilem Material (44) mit einem ersten und einem zweiten Endabschnitt (42, 46) aufweist, wobei der erste Endabschnitt eine Mehrzahl langgestreckter Streifen (40) aufweist, die von dem ersten Endabschnitt des Blatts zu Außenendbereichen (52) abstehen, wobei in dem Blatt (44) Öffnungen (48) ausgebildet sind, wobei die langgestreckten Streifen durch die in dem Blatt gebildeten Öffnungen hindurchgezogen werden, um die allgemein zylindrische Öffnung (50) zu bilden, wobei die Öffnung so ausgebildet ist, dass sie sich verengt, wenn die langgestreckten Streifen (40) und das zweite Ende (46) des Blatts in entgegengesetzte Richtungen gezogen werden.
3. Stent-Krimpwerkzeug nach Anspruch 2, das ferner ein Paar von Klemmen (38) aufweist, um die Außenendbereiche (52) der langgestreckten Streifen (40) und einen Abschnitt des zweiten Endes (46) des Blatts (44) des Schleifenabschnitts (12) an den Schwenkarmabschnitten zu befestigen, wobei die allgemein zylindrische Öffnung (50) auf dem Mittelabschnitt (16) aufliegt.
4. Stent-Krimpwerkzeug (10) nach Anspruch 3, wobei an jedem Schwenkarmabschnitt (18, 20) ein Eingriffsmittel (32) ausgebildet ist, und wobei die Klemmen (38) komplementäre Eingriffsabschnitte (54) aufweisen, die zum Eingriff mit den Schwenkarmeingriffsmitteln dienen, um Außenendabschnitte (52) und das zweite Ende (46) des Blatts (44) des Schleifenabschnitts (12), die daran positioniert sind, zu halten.
5. Stent-Krimpwerkzeug (10) nach Anspruch 4, wobei das Blatt aus flexilem Material (44) ferner eine Oberseite (22) aufweist und jeder Schwenkarmabschnitt (18, 20) ferner eine Mehrzahl von Seitenrändern (36) aufweist, wobei in jedem Seitenrand eine Vertiefung (34) angeordnet ist, und wobei das Eingriffsmittel (32) einen in der Oberseite jedes Schwenkarmabschnitts ausgebildeten Schlitz aufweist, und wobei die komplementären Eingriffsabschnitte (54) der Klemmen (38) jeweils eine an ihrer Unterseite (56) angeordnete Leiste aufweisen, die dazu ausgelegt ist, in einen entsprechenden Schlitz (32) zu passen, und wobei eine Mehrzahl von Klemmenenden (58) dazu ausgelegt ist, in die Vertiefungen (34) in den Seitenrändern (36) der Schwenk-
- 5 armabschnitte (18, 20) zu passen.
6. Stent-Krimpwerkzeug (10) nach Anspruch 1, das ferner eine Schutzschicht (60) aufweist, die den Schleifenabschnitt (12) abdeckt und die verhindert, dass die Schwenkarmabschnitte (18, 20) vorzeitig von dem Mittelabschnitt nach unten verschwenkt werden.
- 10 7. Stent-Krimpwerkzeug (10) nach Anspruch 1, wobei der Basisabschnitt (14) aus einem Einzelblock aus allgemein starrem Material gebildet ist, wobei die Schwenkarmabschnitte (18, 20) und der Mittelabschnitt (16) durch in dem starren Material gebildete längliche Slitze (26, 28) gebildet sind, die sich von einer Oberseite (22) zu nahe einer Unterseite (24) des einzelnen Materialblocks erstrecken, wobei sie ungeschlitzte Materialbereiche belassen, die ein Paar von Gelenken (30A, 30B) bilden, so dass bei Gebrauch die Schwenkarmabschnitte an dem Gelenkpaar verschwenkt werden können.
- 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100 105 110 115 120 125 130 135 140 145 150 155 160 165 170 175 180 185 190 195 200 205 210 215 220 225 230 235 240 245 250 255 260 265 270 275 280 285 290 295 300 305 310 315 320 325 330 335 340 345 350 355 360 365 370 375 380 385 390 395 400 405 410 415 420 425 430 435 440 445 450 455 460 465 470 475 480 485 490 495 500 505 510 515 520 525 530 535 540 545 550 555 560 565 570 575 580 585 590 595 600 605 610 615 620 625 630 635 640 645 650 655 660 665 670 675 680 685 690 695 700 705 710 715 720 725 730 735 740 745 750 755 760 765 770 775 780 785 790 795 800 805 810 815 820 825 830 835 840 845 850 855 860 865 870 875 880 885 890 895 900 905 910 915 920 925 930 935 940 945 950 955 960 965 970 975 980 985 990 995 1000 1005 1010 1015 1020 1025 1030 1035 1040 1045 1050 1055 1060 1065 1070 1075 1080 1085 1090 1095 1100 1105 1110 1115 1120 1125 1130 1135 1140 1145 1150 1155 1160 1165 1170 1175 1180 1185 1190 1195 1200 1205 1210 1215 1220 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5225 5230 5235 5240 5245 5250 5255 5260 5265 5270 5275 5280 5285 5290 5295 5300 5305 5310 5315 5320 5325 5330 5335 5340 5345 5350 5355 5360 5365 5370 5375 5380 5385 5390 5395 5400 5405 5410 5415 5420 5425 5430 5435 5440 5445 5450 5455 5460 5465 5470 5475 5480 5485 5490 5495 5500 5505 5510 5515 5520 5525 5530 5535 5540 5545 5550 5555 5560 5565 5570 5575 5580 5585 5590 5595 5600 5605 5610 5615 5620 5625 5630 5635 5640 5645 5650 5655 5660 5665 5670 5675 5680 5685 5690 5695 5700 5705 5710 5715 5720 5725 5730 5735 5740 5745 5750 5755 5760 5765 5770 5775 5780 5785 5790 5795 5800 5805 5810 5815 5820 5825 5830 5835 5840 5845 5850 5855 5860 5865 5870 5875 5880 5885 5890 5895 5900 5905 5910 5915 5920 5925 5930 5935 5940 5945 5950 5955 5960 5965 5970 5975 5980 5985 5990 5995 6000 6005 6010 6015 6020 6025 6030 6035 6040 6045 6050 6055 6060 6065 6070 6075 6080 6085 6090 6095 6100 6105 6110 6115 6120 6125 6130 6135 6140 6145 6150 6155 6160 6165 6170 6175 6180 6185 6190 6195 6200 6205 6210 6215 6220 6225 6230 6235 6240 6245 6250 6255 6260 6265 6270 6275 6280 6285 6290 6295 6300 6305 6310 6315 6320 6325 6330 6335 6340 6345 6350 6355 6360 6365 6370 6375 6380 6385 6390 6395 6400 6405 6410 6415 6420 6425 6430 6435 6440 6445 6450 6455 6460 6465 6470 6475 6480 6485 6490 6495 6500 6505 6510 6515 6520 6525 6530 6535 6540 6545 6550 6555 6560 6565 6570 6575 6580 6585 6590 6595 6600 6605 6610 6615 6620 6625 6630 6635 6640 6645 6650 6655 6660 6665 6670 6675 6680 6685 6690 6695 6700 6705 6710 6715 6720 6725 6730 6735 6740 6745 6750 6755 6760 6765 6770 6775 6780 6785 6790 6795 6800 6805 6810 6815 6820 6825 6830 6835 6840 6845 6850 6855 6860 6865 6870 6875 6880 6885 6890 6895 6900 6905 6910 6915 6920 6925 6930 6935 6940 6945 6950 6955 6960 6965 6970 6975 6980 6985 6990 6995 7000 7005 7010 7015 7020 7025 7030 7035 7040 7045 7050 7055 7060 7065 7070 7075 7080 7085 7090 7095 7100 7105 7110 7115 7120 7125 7130 7135 7140 7145 7150 7155 7160 7165 7170 7175 7180 7185 7190 7195 7200 7205 7210 7215 7220 7225 7230 7235 7240 7245 7250 7255 7260 7265 7270 7275 7280 7285 7290 7295 7300 7305 7310 7315 7320 7325 7330 7335 7340 7345 7350 7355 7360 7365 7370 7375 7380 7385 7390 7395 7400 7405 7410 7415 7420 7425 7430 7435 7440 7445 7450 7455 7460 7465 7470 7475 7480 7485 7490 7495 7500 7505 7510 7515 7520 7525 7530 7535 7540 7545 7550 7555 7560 7565 7570 7575 7580 7585 7590 7595 7600 7605 7610 7615 7620 7625 7630 7635 7640 7645 7650 7655 7660 7665 7670 7675 7680 7685 7690 7695 7700 7705 7710 7715 7720 7725 7730 7735 7740 7745 7750 7755 7760 7765 7770 7775 7780 7785 7790 7795 7800 7805 7810 7815 7820 7825 7830 7835 7840 7845 7850 7855 7860 7865 7870 7875 7880 7885 7890 7895 7900 7905 7910 7915 7920 7925 7930 7935 7940 7945 7950 7955 7960 7965 7970 7975 7980 7985 7990 7995 8000 8005 8010 8015 8020 8025 8030 8035 8040 8045 8050 8055 8060 8065 8070 8075 8080 8085 8090 8095 8100 8105 8110 8115 8120 8125 8130 8135 8140 8145 8150 8155 8160 8165 8170 8175 8180 8185 8190 8195 8200 8205 8210 8215 8220 8225 8230 8235 8240 8245 8250 8255 8260 8265 8270 8275 8280 8285 8290 8295 8300 8305 8310 8315 8320 8325 8330 8335 8340 8345 8350 8355 8360 8365 8370 8375 8380 8385 8390 8395 8400 8405 8410 8415 8420 8425 8430 8435 8440 8445 8450 8455 8460 8465 8470 8475 8480 8485 8490 8495 8500 8505 8510 8515 8520 8525 8530 8535 8540 8545 8550 8555 8560 8565 8570 8575 8580 8585 8590 8595 8600 8605 8610 8615 8620 8625 8630 8635 8640 8645 8650 8655 8660 8665 8670 8675 8680 8685 8690 8695 8700 8705 8710 8715 8720 8725 8730 8735 8740 8745 8750 8755 8760 8765 8770 8775 8780 8785 8790 8795 8800 8805 8810 8815 8820 8825 8830 8835 8840 8845 8850 8855 8860 8865 8870 8875 8880 8885 8890 8895 8900 8905 8910 8915 8920 8925 8930 8935 8940 8945 8950 8955 8960 8965 8970 8975 8980 8985 8990 8995 9000 9005 9010 9015 9020 9025 9030 9035 9040 9045 9050 9055 9060 9065 9070 9075 9080 9085 9090 9095 9100 9105 9110 9115 9120 9125 9130 9135 9140 9145 9150 9155 9160 9165 9170 9175 9180 9185 9190 9195 9200 9205 9210 9215 9220 9225 9230 9235 9240 9245 9250 9255 9260 9265 9270 9275 9280 9285 9290 9295 9300 9305 9310 9315 9320 9325 9330 9335 9340 9345 9350 9355 9360 9365 9370 9375 9380 9385 9390 9395 9400 9405 9410 9415 9420 9425 9430 9435 9440 9445 9450 9455 9460 9465 9470 9475 9480 9485 9490 9495 9500 9505 9510 9515 9520 9525 9530 9535 9540 9545 9550 9555 9560 9565 9570 9575 9580 9585 9590 9595 9600 9605 9610 9615 9620 9625 9630 9635 9640 9645 9650 9655 9660 9665 9670 9675 9680 9685 9690 9695 9700 9705 9710 9715 9720 9725 9730 9735 9740 9745 9750 9755 9760 9765 9770 9775 9780 9785 9790 9795 9800 9805 9810 9815 9820 9825 9830 9835 9840 9845 9850 9855 9860 9865 9870 9875 9880 9885 9890 9895 9900 9905 9910 9915 9920 9925 9930 9935 9940 9945 9950 9955 9960 9965 9970 9975 9980 9985 9990 9995 10000 10005 10010 10015 10020 10025 10030 10035 10040 10045 10050 10055 10060 10065 10070 10075 10080 10085 10090 10095 10100 10105 10110 10115 10120 10125 10130 10135 10140 10145 10150 10155 10160 10165 10170 10175 10180 10185 10190 10195 10200 10205 10210 10215 10220 10225 10230 10235

- terung der allgemein zylindrischen Öffnung nach radial aussen zu ermöglichen, damit die Stent-und-Katheter-Anordnung entfernt werden kann.
9. Verfahren nach Anspruch 8, wobei der Schleifenabschnitt (12) ein Blatt aus einem flexiblen Material (44) mit einem ersten und einem zweiten Ende (42, 46) aufweist, wobei der erste Endabschnitt eine Mehrzahl langgestreckter Streifen (40) aufweist, die von dem ersten Endabschnitt des Blatts zu Außenbereichen (42) abstehen, wobei das Blatt von Öffnungen (48) durchsetzt ist, wobei die langgestreckten Streifen durch die in dem Blatt ausgebildeten Öffnungen hindurchgezogen werden, um die allgemein zylindrische Schleifenöffnung zu bilden, wobei die Schleifenöffnung konfiguriert ist, um sich zu verengen, wenn die langgestreckten Streifen und das zweite Ende (44) des Blatts in entgegengesetzte Richtungen gezogen werden.
10. Verfahren nach Anspruch 8, wobei die Vorrichtung mit einer entfernbaren Schutzschicht (60) abgedeckt ist, um den Schleifenabschnitt (12) zu schützen und um zu verhindern, dass die Schwenkarmabschnitte (28) vorzeitig von dem Mittelabschnitt verschwenkt werden.
- Revendications**
1. Outil de serrage de stent (10) pour fixer provisoirement un stent (A) sur un ensemble formant cathéter (D), comprenant :
- une partie de base (14) ayant une partie intermédiaire (16) et des parties de bras pivotants (18, 20) fixées de manière pivotante sur la partie intermédiaire ; et
- une partie en boucle (12) fixée sur les parties de bras pivotants (18, 20), destinée à être utilisée afin de supporter une partie de l'ensemble formant cathéter (D) sur lequel doit être chargé le stent, la partie en boucle (12) ayant une ouverture (50) compressible et sensiblement cylindrique qui peut être comprimée de façon uniforme radialement vers l'intérieur, lorsqu'on applique une force sur lesdites parties de bras pivotants, afin de comprimer sensiblement uniformément et de manière serrée le stent sur l'ensemble formant cathéter.
2. Outil de serrage de stent (10) selon la revendication 1, dans lequel la partie en boucle (12) comprend une feuille de matériau flexible (44) ayant des première et seconde parties d'extrémité (42, 46), la première partie d'extrémité comprenant une pluralité de bandelettes allongées (40) s'étendant depuis la première partie d'extrémité de la feuille jusqu'aux régions d'extrémité terminales (52), la feuille (44) ayant des trous (48) formés à travers elle, dans lesquels les bandelettes allongées sont insérées de manière à former l'ouverture sensiblement cylindrique (50), celle-ci étant susceptible de se resserrer lorsque les bandelettes allongées (40) et la seconde extrémité (46) de la feuille sont tirées dans des directions opposées.
3. Outil de serrage de stent selon la revendication 2, comprenant en outre une paire de pinces (38) destinées à fixer les régions d'extrémité terminales (52) des bandelettes allongées (40) et une partie de la seconde extrémité (46) de la feuille (44) de la partie en boucle (12) sur les parties de bras pivotants, l'ouverture sensiblement cylindrique (50) passant sur la partie intermédiaire (16).
4. Outil de serrage de stent (10) selon la revendication 3, dans lequel chaque partie de bras pivotant (18, 20) présente des moyens de prise (32) et dans lequel les pinces (38) présentent des parties de prise complémentaires (54) adaptées pour venir en prise avec les moyens de prise des bras pivotants afin de retenir les parties d'extrémité terminales (52) et la seconde extrémité (46) de la feuille (44) de la partie en boucle (12).
5. Outil de serrage de stent (10) selon la revendication 4, dans lequel la partie de base (14) présente en outre une surface supérieure (22), chaque partie de bras pivotant (18, 20) présente en outre une pluralité de bords latéraux (36), chaque bord latéral comporte un creux (34), les moyens de prise (32) sont constitués par une rainure ménagée dans la surface supérieure de chaque partie de bras pivotant, les parties de prise complémentaires (54) des pinces (38) présentent chacune une nervure placée sur leur surface inférieure (56) et susceptible de s'insérer dans la rainure correspondante (32), et une pluralité d'extrémités de pince (58) susceptibles de s'insérer dans les creux (34) ménagés dans les bords latéraux (36) des parties de bras pivotants (18, 20).
6. Outil de serrage de stent (10) selon la revendication 1, comprenant en outre une couche protectrice (60) qui recouvre la partie en boucle (12) et qui empêche les parties de bras pivotants (18, 20) d'être pivotées prématurément vers le bas par rapport à la partie intermédiaire.
7. Outil de serrage de stent (10) selon la revendication 1, dans lequel la partie de base (14) est formée à partir d'un seul bloc de matériau généralement rigide, les parties de bras pivotants (18, 20) et la partie intermédiaire (16) sont formées en pratiquant dans

le matériau rigide des fentes longitudinales (26, 28) s'étendant depuis la surface supérieure (22) pour s'approcher d'une surface inférieure (24) du bloc de matériau unique, en laissant des zones de matériau non fendues pour définir une paire d'articulations (30A, 30B), de telle sorte qu'en utilisation, les parties de bras pivotants puissent être pivotées autour de la paire d'articulations.

8. Procédé pour comprimer sensiblement uniformément et de manière serrée un stent intravasculaire (A) sur un ensemble formant cathéter (D), comprenant les étapes consistant à :

prévoir un dispositif (10) comprenant une partie de base (14) ayant une partie intermédiaire (16) et des parties de bras pivotants (18, 20) fixées sur la partie intermédiaire, et une partie en boucle (12) destinée à être utilisée pour supporter une partie de l'ensemble formant cathéter (D) sur laquelle peut être placé le stent (A), la partie en boucle ayant une ouverture (50) compressible et sensiblement cylindrique qui est compressible de façon uniforme radialement vers l'intérieur lorsqu'on lui applique une force afin de comprimer sensiblement uniformément et de manière serrée le stent sur la partie de cathéter, la partie en boucle ayant des parties d'extrémité (42, 46) fixées sur les parties de bras pivotants ;

placer une partie de l'ensemble formant cathéter, sur lequel est placé le stent, à l'intérieur de la partie en boucle ;

déplacer de manière pivotante les parties de bras pivotants par rapport à la partie intermédiaire pour déplacer les parties d'extrémité de la partie en boucle dans des directions opposées, réduisant ainsi le diamètre de l'ouverture sensiblement cylindrique afin d'appliquer une force de compression qui comprime le stent radialement vers l'intérieur, et de comprimer sensiblement uniformément et de manière serrée le stent sur la partie de cathéter ; et

relâcher la force de compression pour permettre la dilatation radialement vers l'extérieur de l'ouverture sensiblement cylindrique et permettre le retrait du stent et de l'ensemble formant cathéter.

9. Procédé selon la revendication 8, dans lequel la partie en boucle (12) comprend une feuille de matériau flexible (44) ayant des première et seconde extrémités (42, 46), la première partie d'extrémité ayant une pluralité de bandelettes allongées (40) s'étendant de la première partie d'extrémité de la feuille vers les régions d'extrémité terminales (52), la feuille comportant des trous (48) ménagés à travers celle-ci, dans lesquels les bandelettes allon-

gées sont insérées pour former l'ouverture de boucle sensiblement cylindrique, laquelle ouverture de boucle est configurée pour se resserrer lorsque les bandelettes allongées et la seconde extrémité (44) de la feuille sont tirées dans des directions opposées.

10. Procédé selon la revendication 8, dans lequel le dispositif est recouvert d'une couche protectrice amoebique (60) pour protéger la partie en boucle (12) et pour empêcher que les parties de bras pivotants (18, 20) ne pivotent prématurément par rapport à la partie intermédiaire.

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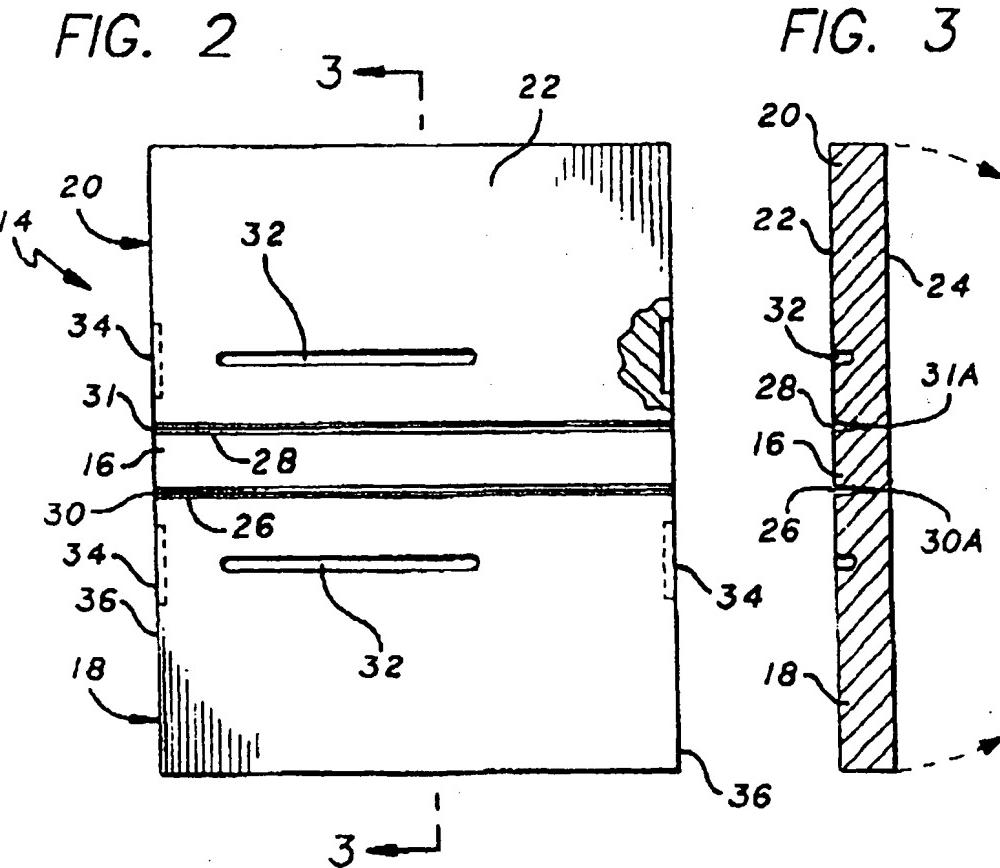
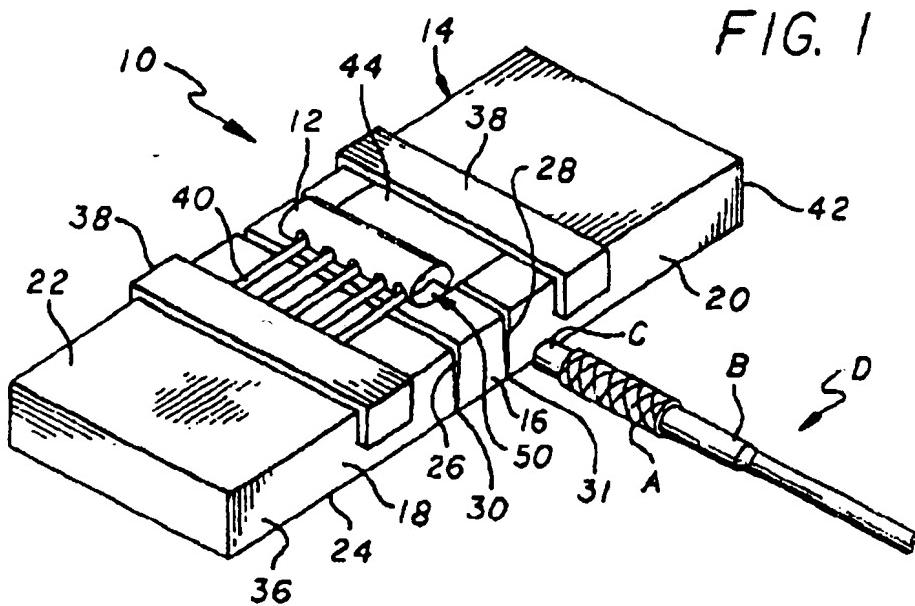


FIG. 4

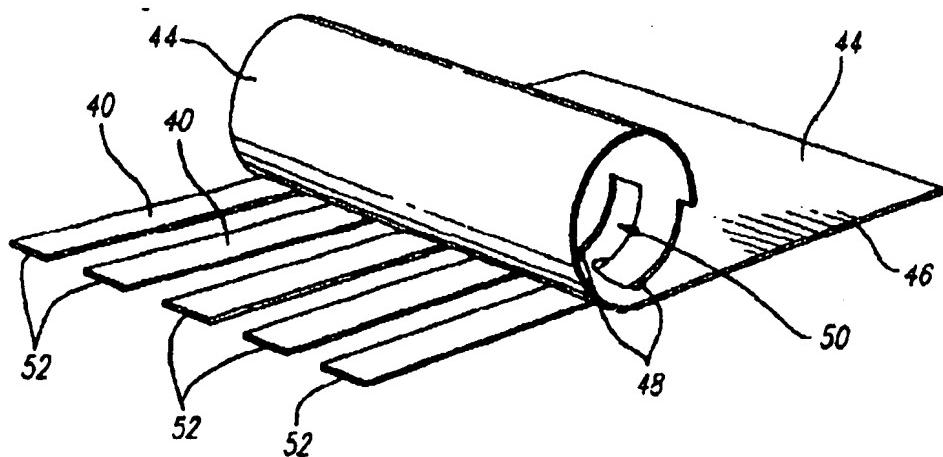


FIG. 5

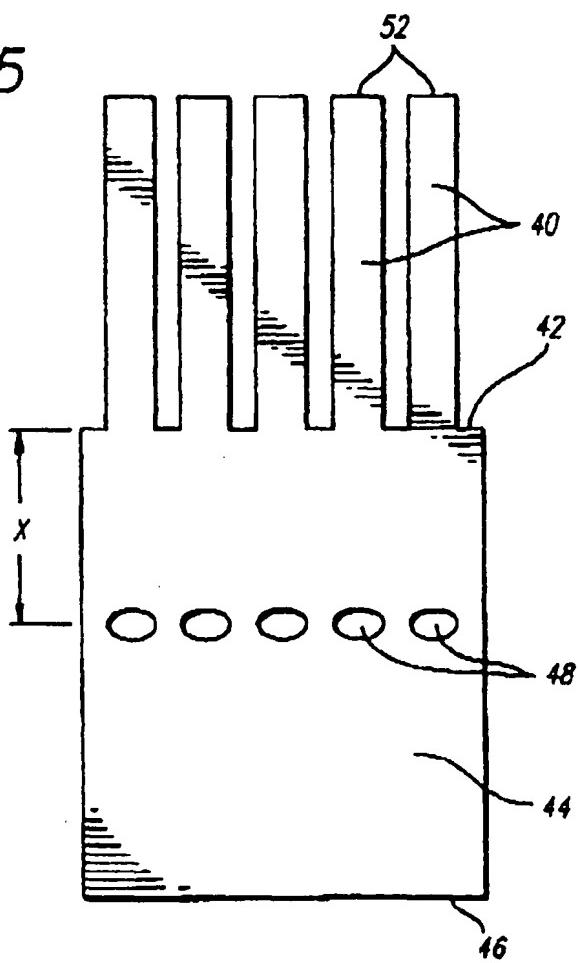


FIG. 6

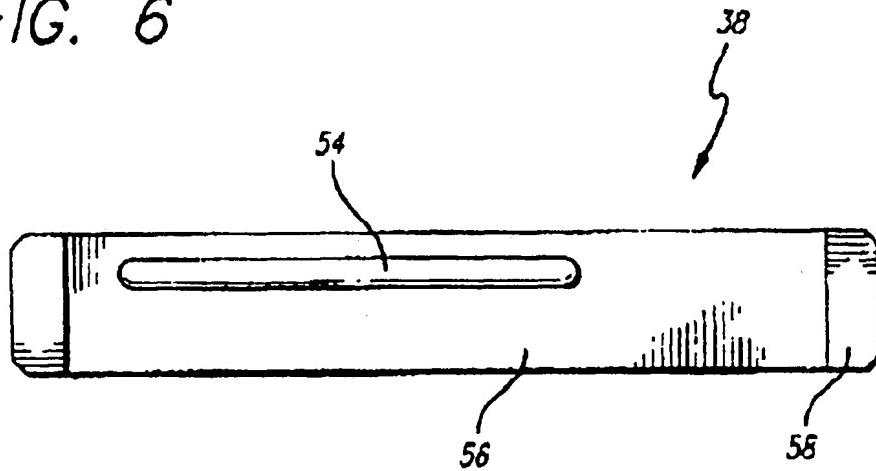


FIG. 7

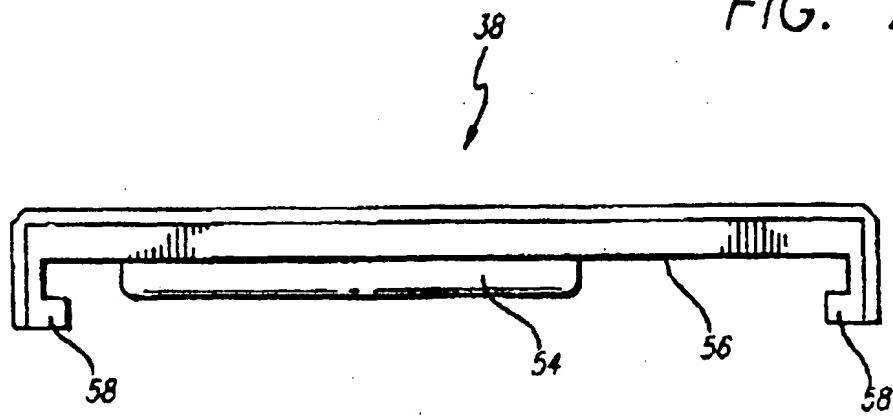


FIG. 8

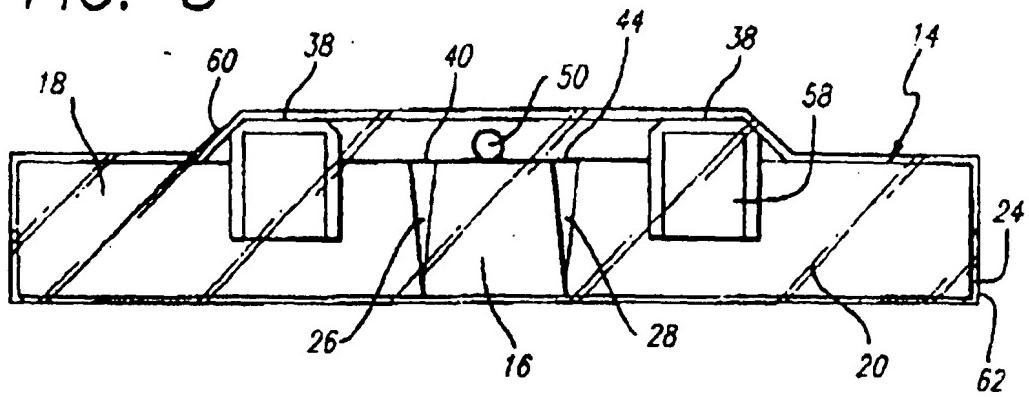


FIG. 10

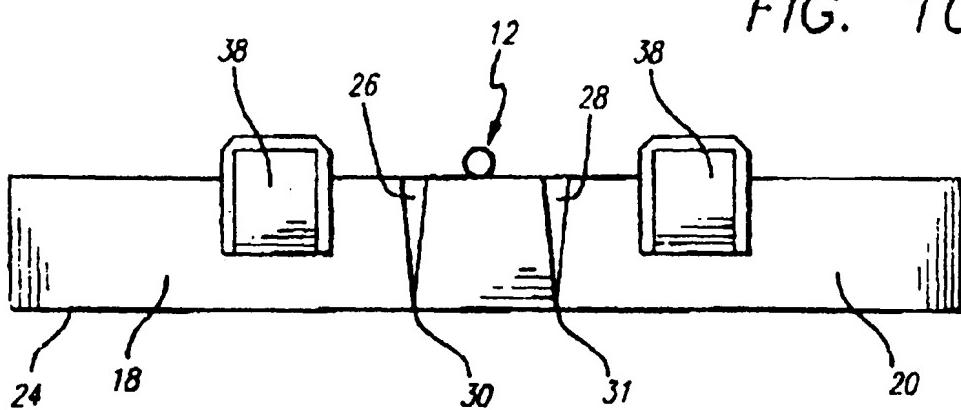
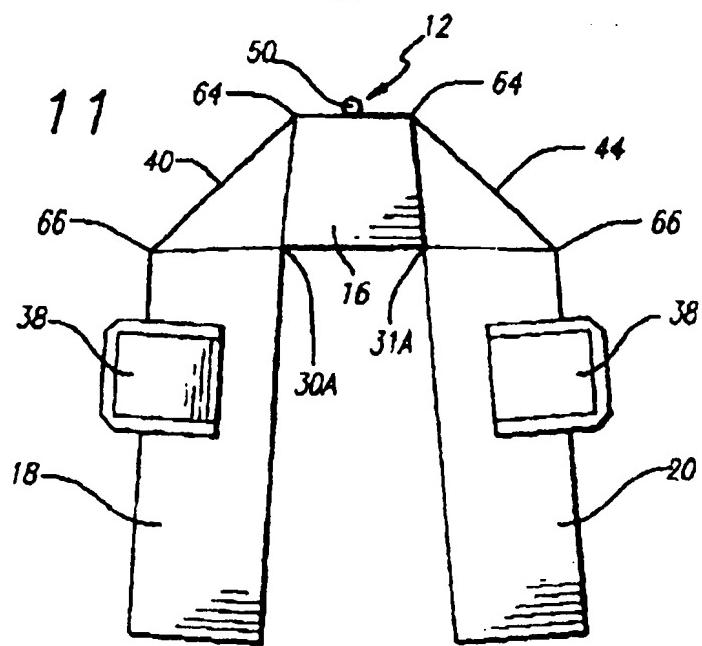


FIG. 11



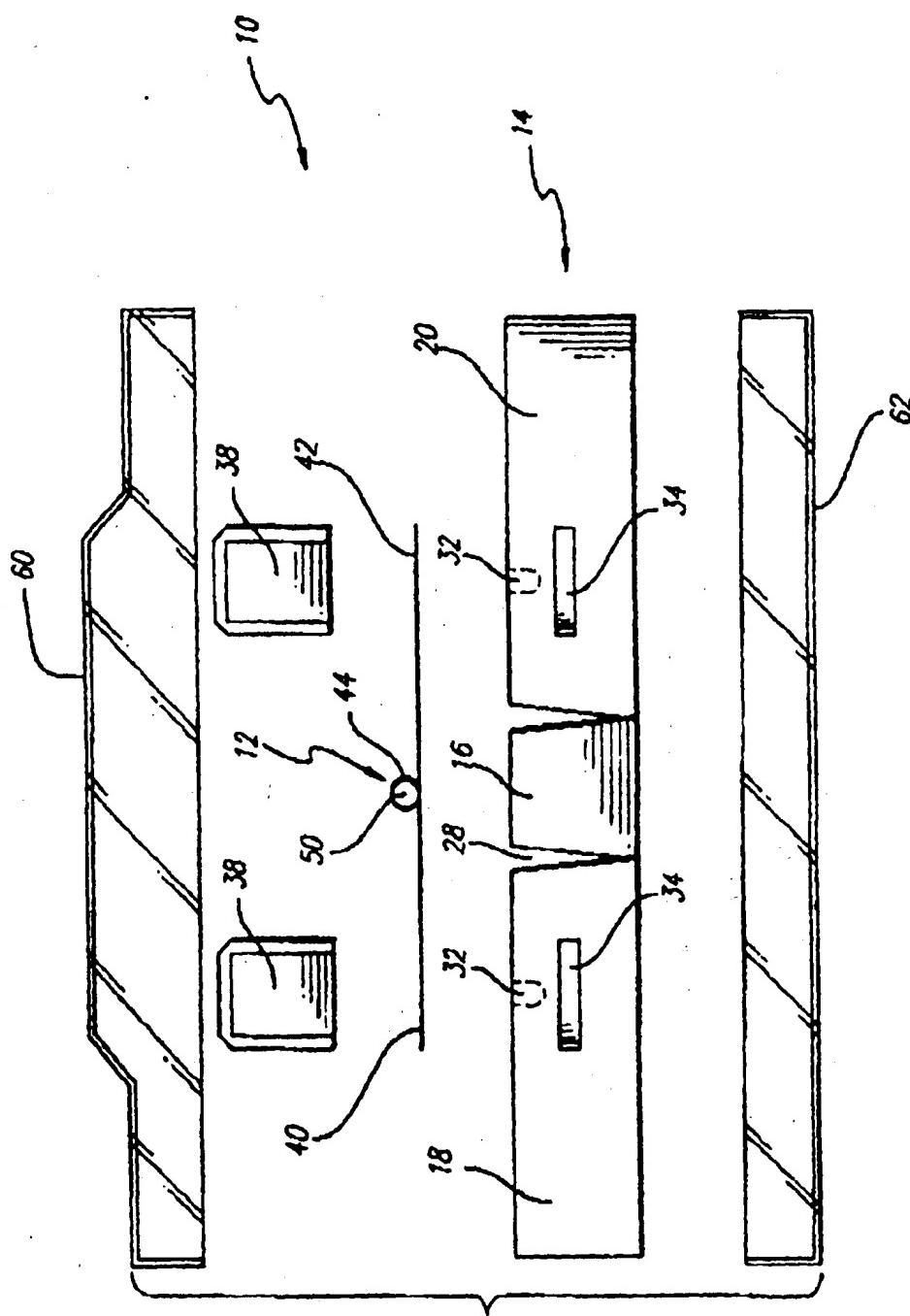


FIG. 9